



Treatment and Participant Adherence

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Session Plan

- ◆ What are
 - **treatment adherence** (fidelity)?
 - **participant adherence**?
- ◆ Why do they matter?
- ◆ How to
 - induce/enhance them
 - assess them
- ◆ Current issues





Treatment Adherence

Responsible Parties: Investigator & Interventionists

- ◆ **Treatment integrity:** was the treatment delivered as intended
 - **Conceptually.** Did the developed treatment capture the theoretically active ingredients?
 - **Pragmatically.** Did interventionists follow the treatment plan?

- ◆ **Treatment differentiation:** did the treatment differ from control condition as intended?
 - **Conceptually.** Were non-specific treatment factors controlled (e.g., attention, contact, credibility)?
 - **Pragmatically.** Did the treatments “bleed?”

(Moncher & Prinz, 1991)



Why Does Treatment Fidelity Matter?

- ◆ **Preserves internal validity** against
 - **Type I error**: significant treatment effect, but arises because unintended treatment ingredient was added to the intervention
 - **Type II error**: no treatment effect, but treatment wasn't actually administered as intended
- ◆ **Improves power** (research efficiency) by reducing unintended variability in treatment effect
- ◆ **Supports external validity** by allowing replication, dissemination



Participant Adherence

Responsible Party: Participants

- ◆ **Receipt:** was the treatment received and/or comprehended by the patient?
 - **Drug:** did patient get prescription? receive pills?
 - **Behavioral:**
 - conscious presence: did patient attend treatment session? access web-based program? view video? read e-mails?
 - comprehension: *learn* skills? Did they understand and can they perform them?
- ◆ **Enactment:** does patient use what they learned (take drug, practice skills) outside of treatment in daily life?

(Lichstein et al's (1994) Treatment Implementation Model



**Treatment
Adherence**
(Delivery)

Did you throw a baseball?
(vs. dropping it or throwing a
watermelon or a fur coat)



Receipt

Did s/he catch the
ball? (present,
conscious,
understand what's
expected)



Did s/he tag the
batter out? (behave
as advised)

Enactment

**Participant
Adherence**



Treatment Penetration



Treatment
Delivery

Participant Adherence

Clinical
Outcome

DPP

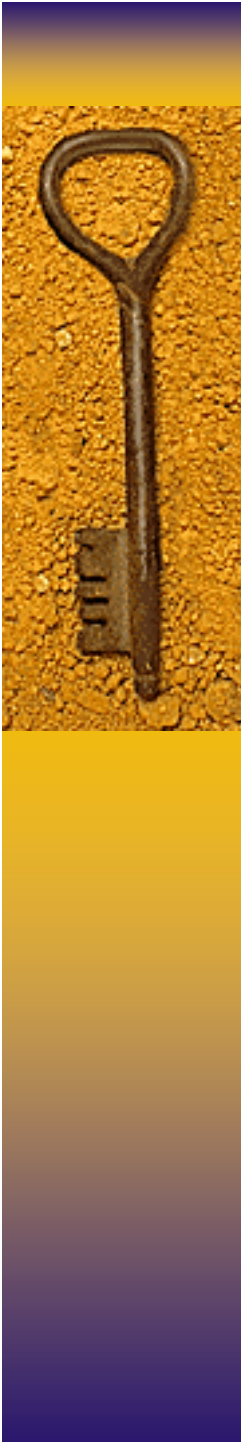
Diet, Exercise

Weight loss,
Improved HbA1C

Smoking
Cessation
Tx

Relaxation, NRT

Quit Smoking



Induction versus Assessment of Adherence

◆ Induction

- Actively doing things to improve treatment and participant adherence

◆ Assessment

- Monitoring and measuring how well treatment was delivered as intended and how fully participants complied with recommendations



	Induce	Assess
Treatment Adherence		
Participant Adherence		



Inducing Treatment Adherence: Maximizing Fidelity

◆ Treatment manuals


- For experimental and control treatments
 - Explain theoretical rationale, treatment principles, provide if/then guidelines
 - Per session script integrating goals interventionist/participant roles/materials
 - Dosing criteria (e.g., are spontaneous phone calls from patients between sessions permitted? Booster sessions?)
 - Which kinds of latitude are and aren't allowed? (conducting sessions by telephone or e-mail? Child allowed in session?)
- ❖ **No robots need apply** (except for computerized treatments)
- ❖ **Clinical judgment needed**



Inducing Treatment Adherence: Maximizing Fidelity

◆ **Centralized training of interventionists**

- Set criteria and procedures for selecting therapists
- Anticipate attrition!! Choose and train extra therapists.
- Model the intervention “live” or via video
- Role plays with observation
- Trial with “sample” participant – audiotaped with feedback
- Trial run at site
- A priori performance criteria



Inducing Treatment Adherence: Maintaining Fidelity

- ◆ **Supervise therapists**
 - Do therapists *understand* the intervention?
- ◆ **Monitor protocol adherence checklists**
 - Record sessions
 - Topics covered, time spent
 - A priori performance criteria
- ◆ **Hold training booster sessions** – guard against drift



Assessing Treatment Adherence (Fidelity)

- ◆ Direct observation, videotapes, audiotapes, session/process notes
- ◆ Best if random rather than fixed assessment schedule
- ◆ Monitor multiple “channels:” content, style
- ◆ Assess degree of tailoring across sites, demographic subgroups
- ◆ Assess therapist characteristics (gender, age, training, warmth, treatment allegiance)



Assessing Treatment Adherence

◆ Over time

- Assess stability, watch for drift
- Check for omission of required elements
- Check for inclusion of unintended elements

◆ Between treatment conditions

- Watch for bleeding/contamination across treatments
- Hardest when same therapists deliver both interventions
- Watch for “treatment delivery” by patients in different intervention arms (especially household members)



Inducing Participant Adherence

◆ Patient selection

- Do they have/care about the target problem?
- Willingness to be randomized to either condition
- Felt personal susceptibility
- IQ, education, run-in, but representativeness

◆ Enhance motivational salience (MI)

◆ In session rehearsal

◆ Clarity/complexity of delivery (reading level, cartoons, repetition)

◆ Tools (handouts, tapes, websites, prompts)



Inducing Participant Adherence

- ◆ **Heighten incentives for treatment attendance, retention**
- ◆ **Remove access barriers** (childcare, telephone delivery, transportation, web-based or e-mail treatment, take treatment to community)
- ◆ **Lower treatment burden** (minimalist interventions, tailored mailings, media, billboard)



Inducing participant adherence: Getting patients to apply what they learned

- ◆ Environmental prompts
- ◆ Goal setting
- ◆ Treatment contracts
- ◆ Contingencies/rewards
- ◆ Problem-solving about enactment barriers
- ◆ Self-monitoring
- ◆ Social support



Participant Adherence Assessment

- ◆ Session attendance
- ◆ Acquisition of supplied treatment tools (meal replacements, pedometer, exercise equipment)
- ◆ Self-reported reading of tailored mailings, media exposure)
- ◆ Pre-post knowledge tests
- ◆ Observer rating
- ◆ Self-report of confidence in applying skills
- ◆ Completion of homework exercises
- ◆ Physiological/biomarker monitoring



Participant Adherence Assessment

- ◆ **Direct measurement** (MEMS caps, heart rate monitor, accelerometer, drug blood level, dietary metabolite, grocery receipts, gym visits, website hits)
- ◆ **Collateral report** (spouse, roommate)
- ◆ **Written logs** (food and activity diaries, pack wraps, skill rehearsal log)
- ◆ **Retrospective self-report** – 24 hour recall, PDA
 - Best if *short interval* and *unpredictable*

Current Issues

- ❖ treatment fidelity versus collaborative reinvention
- ❖ individual vs. group/community/systems interventions

